

### REMARKS

The September 24, 2003 Official Action and references cited therein have been carefully reviewed.

At page 3 of the Official Action, the Examiner has rejected claim 2 under 35 U.S.C. §112, second paragraph, asserting that the claim is indefinite for inclusion of the term "optionally".

Claims 1, and 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 3-4, 6-8, and 10-13 of U.S. Patent Application No. 10/321,195 (hereinafter '95 application).

At page 5 of the Official Action, the Examiner has rejected claims 2 and 7 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1, 3-4, 6-8, and 10-13 of the '95 application in view of US Patent 6,251,604 to Lietz.

The foregoing constitutes the entirety of the objections and rejections raised in the September 24, 2003 Official Action. In light of the Terminal Disclaimer under 37 C.F.R. §1.321, and the following remarks, each of the above-noted rejections under the judicially created doctrine of obviousness-type double patenting and 35 U.S.C. §§112, second paragraph is respectfully traversed.

### **THE AMENDMENT TO CLAIM 2 CLARIFIES**

#### **THE METES AND BOUNDS OF THE CLAIM**

The Examiner alleges the term "optionally" in step c) of claim 2 renders the claim indefinite as it is allegedly unclear whether the steps which follow the term are required limitations

of the method. This allegation is respectfully traversed.

Applicants reiterate that it is clear that the practice of the method of claim 1, wherein no primer sequences are added, will result in the generation of a population of variant polynucleotide sequences due to the annealing the exonuclease digested single stranded fragments and PCR amplification of the same. The specification and claims as originally filed explicitly disclose that the further addition of primers is optional performed to introduce greater sequence variability. It is, therefore, submitted that the skilled person would readily appreciate that the inventive method of the invention optionally includes the additional feature of "adding primer sequences" to further generate variant polynucleotides in step c). However, in order to advance prosecution of this application claim 2 has been amended to recite that the method "further" comprises the addition of such primer sequences. It is respectfully submitted that the instant amendment removes any perceived lack of clarity from the claim. Accordingly, the rejection under 35 U.S.C. §112, second paragraph should be withdrawn.

**CLAIMS 1 AND 3-6 ARE PATENTABLE OVER CLAIMS 1, 3, 4, 6-8, AND 10-13 OF THE '195 APPLICATION IN LIGHT OF THE TERMINAL DISCLAIMER SUBMITTED HEREWITH**

Applicants submit that Claims 1 and 3-6 are directed to a patentably distinct method than the method claimed in claims 1, 3-4, 6-8, and 10-13 of the '195 application.

However, in order to expedite allowance of the instant application, submitted herewith a terminal disclaimer disclaiming the terminal part of the statutory term of any patent granted on

the above-identified application beyond the expiration date of the full statutory term of any US Patent that issues on the '195 application. In view of this terminal disclaimer, withdrawal of the double patenting rejection of claims 1 and 3-6 is respectfully requested.


It is further submitted that the Terminal Disclaimer also obviates the provisional double-patenting rejection of claims 2 and 7 over claims 1, 3-4, 6-8, 10-13 the '195 application in view of US Patent 6,251,604 to Lietz

#### Conclusion

It is respectfully urged that the rejections set forth in the September 24, 2003 Official Action be withdrawn. In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number given below.

Respectfully submitted,

DANN, DORFMAN, HERRELL AND SKILLMAN  
A Professional Corporation

By   
Kathleen D. Rigaut, Ph.D., J.D.  
PTO Registration No. 43,047

Telephone: (215) 563-4100

Facsimile: (215) 563-4044

Enclosure: Terminal Disclaimer